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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/098,683	03/15/2002	Gary Karlin Michelson	101.0042-05000	7210

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EXAMINER

HO, UYEN T

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/098,683

Applicant(s)

MICHELSON, GARY KARLIN

Examiner

(Jackie) Tan-Uyen T. Ho

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-90 and 92-103 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54-90 and 92-103 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Response to Arguments

1. Applicant's arguments filed 12/18/06 have been fully considered but they are not persuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case the bone growth promoting materials as claimed are well known in the art for use to promote new bone to growth thus it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made and does not include knowledge gleaned from the applicant's disclosure, such a reconstruction is proper.

Supporting for well-known statement, the examiner provides some example of prior arts that teach and clearly provide one skill in the art the knowledge of using the bone growth promoting materials as claimed in order to promote new bone to growth.

- Urist (4,455,256) taught BMP and how to prepare BMP for implantation in bone defect caused by injury, malignancy etc.
- Constantz et al. (5,178,845) disclose that Hydroxyapatite is a naturally occurring calcium phosphate mineral which is the primary constituent of bone and hydroxyapatite compositions including additives, BMP or other proteins (col. 5-6).

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- Tepic et al. (5,211,664) disclose an implant having porous, hollow body filled with BMP, autologous bone, allogenic bone, demineralized bone powder extract, osteogenin, antibiotics or antieoplastic drugs and the implant being made from artificial material including hydroxyapatite ect..
- Urist (4,596,574) discloses a porous ceramic delivery system for BMP.

Regarding the obvious matter of design choice since applicant has not disclosed that having two or more different growth promoting materials would solves any stated problem or for any particular purpose and it appears that the implant would perform equally well with one or more promoting materials since all the materials are for promoting bone growth. Also the references cited above some disclose more than one bone growth materials being used and other disclose one bone growth material can be used to promote bone growth. Thus, at the time the invention was made it would have been obvious to one having ordinary skill in the art would pick out one or more materials to place in the implant as desired to promote bone growth.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 54-90, 92-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ray et al. (5,026,373).

Ray et al. disclose a spinal fusion implant comprising upper and lower surfaces having openings there through, a hollow interior for holding bone graft or bone growth promoting material, an insert end and a trailing end having a rear wall (fig. 1 and 5) and the implant being made from the material as claimed. Ray et al. also disclose the hollow interior having an interior surface with a total surface area about 75% (inherently) and 25% of area perforated (cols. 9-10). Although, Ray et al. do not disclose bone growth promoting material being bone morphogenetic protein, hydroxyapatite, or both the bone growth promoting materials as claimed are well known in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the bone growth promoting materials as claimed in Ray et al's implant in order to promote new bone to growth.

Regarding to the bone growth promoting material, It also would have been obvious matter of design choice to employ more than one bone growth promoting material in the Ray et al. implant, since applicant has not disclosed that having two different growth promoting materials would solves an stated problem or is for any particular purpose and it appears that the implant would perform equally well with one or more promoting materials.

Regarding coating a bone implant, coating a bone implant with the bone growth promoting material is also well known in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to coat the Ray et al. implant with bone growth promoting material in order to provide a better surface for new bone to growth into the implant and forming bone fusion.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and **to prevent possible harassment by multiple assignees**. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 54-90, 92-103 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-84 of U.S. Patent No. 6,758,849. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are anticipated by the claims of the patent.


6. Claims 54-90, 92-103 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-84 of U.S. Patent No. 6,364,880. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are anticipated by the claims of the patent.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is 571-272-4696. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANHTUAN NGUYEN can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


(Jackie) Tan-Uyen T. Ho
Primary Examiner
Art Unit 3731

March 6, 2007